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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--------------------------------|-------------|----------------------|-------------------------|-----------------|
| 10/651,829 | 08/28/2003 | Bryon E. Petersen | 5853-265 | 9385 |
| 7590 06/21/2005 | | | EXAMINER | |
| Stanley A. Kim., Ph.D., Esq | | | GAMETT, DANIEL C | |
| Akerman Senterfitt Suite 400 | | | ART UNIT | PAPER NUMBER |
| 222 Lakeview Avenue | | | 1647 | |
| West Palm Beach, FL 33402-3188 | | | DATE MAILED: 06/21/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|--|---|----------------------------------|---|-----------------|--|--|--|
| Office Action Summary | | 10/651,829 | PETERSEN ET A | PETERSEN ET AL. | | | |
| | | Examiner | Art Unit | | | | |
| | | Daniel C. Gamett | 1647 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed | on <u>18 A<i>pril</i> 2005</u> . | | • | | | |
| 2a) <u></u> □ | |)⊠ This action is non-fina | | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 5) | | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| Attachment(s) | | | | | | | |
| 2) Notice 3) Infor | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PT rmation Disclosure Statement(s) (PTO-1449 or P er No(s)/Mail Date 07/12/204 06/02/05. | O-948) TO/SB/08) 5) 🔲 | Interview Summary (PTO-413) Paper No(s)/Mail Date Notice of Informal Patent Application (PTOther: | го-152) | | | |

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DETAILED ACTION

1. Applicant's election without traverse of claims 11-20 and election of species βIII tubulin, in the reply filed on 04/18/2005 is acknowledged. The amendment of 04/18/2005 has been entered in full. In view of the amendment and the election, Claims 1-10 and 13-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 04/18/2005.

Claim Objections

2. Claim 11 is objected to because of the following informalities: 'Media' should be changed to 'medium'. A singular cell is cultured a singular medium. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 11, the expression "increases cAMP concentration" is vague because there is no indication as to what value would form the baseline to indicate an increase or how much of an increase is required. In claim 12, the recitation of a marker implies that a set of markers will then be recited, whereas only one marker is actually claimed. Amending the claim to recite *the* marker would maintain clarity as long as only one marker is claimed and obviate this rejection.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Rao, *et al.*, US Patent 6830927, issued December 14, 2004, filed May 6, 1998. Claim 11 is drawn to a cell that expresses a neural phenotype, wherein the cell is cultured in medium comprising an agent that increases cAMP concentration in the cell; claim 12 specifies that the cell of claim 11 expresses the marker βIII tubulin. Rao *et al.*, teach at col. 27, line 39- col. 28, line 3, that cultivation with dibutyl cAMP causes neural crest cells, which initially express at least one neural marker, p75, to differentiate into neural derivatives that express βIII tubulin, GFAP, and other markers typical of neural derivatives, thus fully meeting all of the limitations of claims 11 and 12.
- 7. Claim 11 rejected under 35 U.S.C. 102(b) as being anticipated by Ma *et al.*, Nat. Neurosci. 2(1):24-30, 1999. Ma *et al.* teach (throughout) incubation of neuronal cultures with Sp-cAMPS, an analog that increases intracellular cAMP, thus fully meeting the limitations of claim 11.

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Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272

1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the

organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG

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18 June 2005

BRENDA BRUMBACK

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SUPERVISORY PATENT EXAMINER

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